9.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: RITA® StarBurst™ XLi Electrosurgical Device Common/Classification Name: Electrosurgical cutting and coagulation device
Name of Marketed Device	RITA Medical Systems Inc. – Model 90 Electrosurgical Device
Classification	Class II
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The StarBurst XLi Electrosurgical Device is designed to supply energy (generated by the RITA Medical Systems' electrosurgical generator) for use in electrosurgery and is designed for the following: • Incorporation of multiple needles on each probe minimizing the number of invasive accesses necessary to achieve desired lesions. • Provide a minimally invasive laparoscopic, percutaneous, or intraoperative access to the targeted tissue. • Deliver radiofrequency energy in a controlled fashion to create coagulative necrotic lesions. • Incorporate thermocouples for temperature feedback. • Provide for local delivery of fluid.
Device Description	This RITA device is available in 12-cm and 25-cm lengths for a variety of medical applications. The secondary electrodes deploy out from the trocar tip. The RITA device consists of the following components: *primary electrode*: insulated trocar with a portion exposed as an electrode *secondary electrodes*: array of extendible flexible electrodes that deploy out of the distal end of the trocar *temperature probes*: probes that incorporate temperature sensors. *handle*: handle has markings to indicate how secondary electrode deployment correlates with ablation size. *RF pathway*: connection through nine-pin Lemo connector built into the handle; RF energy is delivered to the primary and secondary electrodes. *fluid infusion*: delivery through ports connected to tubing out the back of the handle *depth indicators*: incremental 1-cm marks on the trocar to denote trocar penetration depth
Performance Data	The StarBurst XLi Electrosurgical Devices were subjected to a battery of electrical, mechanical, and biocompatibility testing to verify that the devices met the specifications. The devices met the specifications and the materials did not elicit toxicological responses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2001

RITA Medical Systems, Inc.
c/o Michael Kwan, Ph.D.
Principal Reviewer/ Office Coordinator
510(k) Review Program
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050-4169

Re: K010060
Trade Name: RITA® StarBurst™ XLi Electrosurgical Device
Regulatory Class: II
Product Code: GEI
Dated: January 5, 2001
Received: January 8, 2001

Dear Dr. Kwan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE

Indications for Use Statement

510(K) Number (if known) K010060

Device Name StarBurst XLi Electrosurgical Device

The StarBurst XLi Electrosurgical Device is designed to supply energy (generated by the RITA Medical Systems' electrosurgical generator) for use in electrosurgery and is designed for the following:

- Incorporation of multiple needles on each probe minimizing the number of invasive accesses necessary to achieve desired lesions.
- Provide a minimally invasive laparoscopic, percutaneous, or intraoperative access to the targeted tissue.
- Deliver radiofrequency energy in a controlled fashion to create coagulative necrotic lesions.
- Incorporate thermocouples for temperature feedback.
- Provide for local delivery of fluid.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K010060

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)